

**REVISED TECHNICAL MEMORANDUM
TOXICITY REFERENCE VALUES FOR AVIAN AND MAMMALIAN RECEPTORS
STEP 3a REFINEMENT OF CONSTITUENTS OF POTENTIAL ECOLOGICAL
CONCERN
FORMER PLAINWELL MILL, INC. PROPERTY
PLAINWELL, MICHIGAN**

INTRODUCTION

This revised Technical Memorandum (Memorandum) identifies the Toxicity Reference Values (TRVs) proposed for use in the refinement of Constituents of Potential Ecological Concern (COPECs) identified in the Screening Level Ecological Risk Assessment (SLERA) completed for the former Plainwell Mill, Inc. property in Plainwell, Allegan County, Michigan. In correspondence dated November 23, 2011, the United States Environmental Protection Agency (U.S. EPA) requested that this Memorandum be prepared and submitted to the agency for review and comment prior to initiating the refinement process, which is Step 3a of the U.S. EPA 8-step process for conducting Ecological Risk Assessments (ERAs). A Technical Memorandum was submitted to U.S. EPA on April 20, 2012 as part of the Remedial Investigation Report, Revision 1. Comments received from U.S. EPA, dated August 30, 2012, requested additional explanation on selection of the TRVs. On September 27, 2012, representatives of Conestoga-Rovers & Associates (CRA), U.S. EPA, and Tetra Tech, contractor to U.S. EPA, participated in a conference call to clarify comments on the April 20, 2012 Technical Memorandum. This revised Technical Memorandum identifies the TRVs proposed for use to evaluate risk to avian and mammalian receptors, along with the rationale for selection of the TRVs.

The SLERA identified several constituents as COPECs based on comparison of maximum concentrations to Ecological Screening Values (ESVs). For several of the constituents, the ESVs were based on Ecological Soil Screening Levels (ECO-SSLs), which have been developed by U.S. EPA. For avian and mammalian receptors, TRVs have been derived for use in development of the ECO-SSLs. The TRVs are either the geometric mean of No Adverse Effect Levels (NOAELs) for the endpoints of reproduction, growth and reproduction, or the highest bounded NOAEL for reproduction and growth less than the lowest bounded Lowest Observed Adverse Effect Level (LOAEL). This approach is intentionally conservative in order to minimize the probability of incorrectly dismissing the potential for risk in the screening process.

For the refinement of COPECs in Step 3a, assumptions regarding exposure and toxicity are evaluated and adjusted, as appropriate, in order to provide a more realistic and site-specific assessment of risk to ecological receptors. Additionally, low end (i.e., no

effect) and high end (i.e., lowest observed effects levels) estimates of risk are typically presented to facilitate risk management decisions. For those constituents that will require evaluation using food chain models, TRVs for low end and high end estimates of risk in Step 3a are identified.

Based on the results of the SLERA and initial analyses conducted for Step 3a, food chain models will be used to assess risk to avian and mammalian receptors exposed to antimony, barium, cadmium, copper, iron, lead, mercury, selenium, zinc, High Molecular Weight (HMW) polycyclic aromatic hydrocarbons (PAHs), acetone, and bis(2-ethylhexyl)phthalate. The proposed TRVs were selected using a tiered approach. For the first tier, low end and high end TRVs identified by U.S. EPA, Region 9 for avian receptors (revision date 02/24/09) and mammalian receptors (revision date 11/21/2002) were selected. If TRVs for a COPEC were not identified by U.S. EPA, Region 9, then source documents for ECO-SSLs for the individual COPECs were consulted as a second tier. The TRVs for the second tier were either taken directly from the source documents or were derived from data presented in the source documents. If the source documents for the ECO-SSLs did not identify TRVs or data, then TRVs identified by Sample et al. (1996) were selected as the third tier. As a fourth tier, TRVs identified in U.S. EPA guidance for conducting ERAs at combustion facilities (U.S. EPA, 1999) were selected.

Table 1 and Table 2 identify the selected TRVs for avian and mammalian receptors, respectively. A discussion of the selection of TRVs for each COPEC for avian and mammalian receptors is provided below.

ANTIMONY

Avian Receptors

The U.S. EPA, Region 9 does not identify TRVs for antimony. The ECO-SSL source document for antimony (U.S. EPA, 2005a) states that no studies were identified that met the criteria for development of a TRV. Sample et. al. (1996) and U.S. EPA guidance for conducting ecological risk assessment at combustion facilities (U.S. EPA, 1999) do not identify TRVs for avian receptors. Based on the absence of data, risk to avian receptors exposed to antimony will not be evaluated.

Mammalian Receptors

The U.S. EPA, Region 9 does not identify TRVs for antimony. The ECO-SSL for mammalian receptors exposed to antimony is based on a TRV of 0.059 mg(dry weight)/kg-day. This TRV is the highest bounded NOAEL below the lowest bounded

LOAEL for effects on reproduction, growth or survival. This conservative TRV of 0.059 mg(dry weight)/kg-day is selected as the low end TRV for mammalian receptors.

The high end TRV for mammalian receptors was derived based on data presented in Table 6.1 of U.S. EPA (2005a). The studies identified in Table 6.1 report results for a variety of test endpoints and exposure routes (i.e., drinking water, gavage, food). Reproduction, growth, and survival are the endpoints most relevant to ecological risk assessment. The exposure route most relevant to ecological risk assessment is ingestion of antimony in food. Based on these selection criteria, six of the studies reported NOAELs. None of the six studies report a LOAEL. The NOAELs for the six studies range from 60.9 mg(dry weight)/kg-day to 2,440 mg (dry weight)/kg-day. The geometric mean of the NOAELs for the six studies, 740 mg (dry weight)/kg-day, is selected as the high end TRV for antimony.

BARIUM

Avian Receptors

The U.S. EPA, Region 9 does not identify a TRV for avian receptors exposed to barium. An ECO-SSL for avian receptors exposed to barium was not calculated due to the availability of only one study (U.S. EPA, 2005b). Sample et al. (1996) identify a NOAEL of 20.8 mg (wet weight)/kg-day and a LOAEL of 41.7 mg (wet weight)/kg-day based on a study using one-day old chicks. The NOAEL of 20.8 mg (wet weight)/kg-day is selected as the low end TRV for the avian receptors. The LOAEL of 41.7 mg (wet weight)/kg-day is selected as the high end TRV.

Mammalian Receptors

The U.S. EPA, Region 9 does not identify TRVs for mammalian receptors. The ECO-SSL for mammalian receptors exposed to barium is based on a TRV of 51.8 mg/kg-day. This TRV is the geometric mean of NOAELs for reproduction and growth. This conservative TRV of 51.8 mg(dry weight)/kg-day is selected as the low end TRV for mammalian receptors.

The high end TRV for mammalian receptors was derived based on data presented in Table 6.1 of U.S. EPA (2005b). The number of studies reporting TRVs for mammalian receptors is relatively limited. Four of the studies identified in Table 6.1 report endpoints of reproduction, growth, or survival and an exposure route of food or gavage. Because only one study reports food as the exposure route, gavage was also included as an exposure route in order to increase the dataset. All four studies reported NOAELs. Two of the studies reported LOAELs. The two reported LOAELs are 197 mg(dry

weight)/kg-day and 198 mg(dry weight)/kg-day, respectively. The geometric mean of these two values, 197 mg(dry weight)/kg-day, is selected as the high end TRV.

CADMIUM

Avian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 0.7 mg (dry weight)/kg-day and high end TRVs of 1.0 mg (dry weight)/kg-day and 10.4 mg (dry weight)/kg-day, respectively, for avian receptors exposed to cadmium. The low end TRV of 0.7 mg (dry weight)/kg-day is based on kidney histology. The high end TRV of 1.0 mg (dry weight)/kg-day is also based on kidney histology. The high end TRV of 10.4 mg (dry weight)/kg-day is based on reproduction and multiple systemic effects, which is more relevant to ecological risk assessment. The low end value of 0.7 mg (dry weight)/kg-day and high end value of 10.4 mg (dry weight)/kg-day identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

Mammalian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 0.06 mg (dry weight)/kg-day and a high end TRV of 2.64 mg (dry weight)/kg-day for mammalian receptors exposed to cadmium. Reproduction is the endpoint for the studies upon which both TRVs are based. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

COPPER

Avian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 2.3 mg (dry weight)/kg-day and a high end TRV of 52.3 mg (dry weight)/kg-day for avian receptors exposed to copper. The low end TRV is based on growth. The high end TRV is based on growth and gizzard erosion. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

Mammalian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 2.67 mg (dry weight)/kg-day and a high end TRV of 632 mg (dry weight)/kg-day for mammalian receptors exposed to copper. The low end TRV is based on immunotoxicology. The high end TRV is based on growth, survival, and water consumption. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

IRON

The U.S. EPA, Region 9 does not identify TRVs for avian and mammalian receptors exposed to iron. U.S. EPA has produced an ECO-SSL document for iron (U.S. EPA, 2003). The document focuses on the geochemistry of iron and its effects on biochemical processes in biota, rather than toxicological effects on avian and mammalian receptors. The document does not identify any TRVs for avian or mammalian receptors. Similarly, Sample et al. (1996) and U.S. EPA guidance for combustion facilities (U.S. EPA, 1999) do not identify TRVs for avian or mammalian receptors. Based on the absence of data, risk to avian and mammalian receptors exposed to iron will not be evaluated.

LEAD

Avian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 0.014 mg (dry weight)/kg-day and a high end TRV of 8.75 mg (dry weight)/kg-day for avian receptors exposed to lead. Reproduction is the endpoint for the studies upon which both TRVs are based. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

Mammalian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 1.0 mg (dry weight)/kg-day and a high end TRV of 241 mg (dry weight)/kg-day for mammalian receptors exposed to lead. The low end TRV is based on renal effects to kidneys. The high end TRV is based on growth and effects on kidneys and liver. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

MERCURY

Avian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 0.039 mg (dry weight)/kg-day and a high end TRV of 0.18 mg (dry weight)/kg-day for avian receptors exposed to mercury. The low end TRV is based on reproduction. The high end TRV is based on survival and neurological effects. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

Mammalian Receptors

The U.S. EPA, Region 9 identifies low end TRVs of 0.027 mg (dry weight)/kg-day and 0.25 mg (dry weight)/kg-day and a high end TRV of 4.0 mg (dry weight)/kg-day for mammalian receptors exposed to mercury. The low end TRV of 0.027 mg (dry weight)/kg-day is based on survival, anorexia, and neurological effects. The low end TRV of 0.25 mg (dry weight)/kg-day and high end TRV are based on reproduction and developmental effects. The lower of the low end values, 0.027 mg (dry weight)/kg-day, is conservatively selected as the low end TRV. The high end value of 4.0 mg (dry weight)/kg-day is selected as the high end TRV.

SELENIUM

Avian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 0.23 mg (dry weight)/kg-day and a high end TRV of 0.93 mg (dry weight)/kg-day for avian receptors exposed to selenium. Reproduction is the endpoint for the studies upon which both TRVs are based. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

Mammalian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 0.05 mg (dry weight)/kg-day and a high end TRV of 1.21 mg (dry weight)/kg-day for mammalian receptors exposed to selenium. The low end TRV is based on renal effects. The high end TRV is based on reproduction. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

ZINC

Avian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 17.2 mg (dry weight)/kg-day and a high end TRV of 172 mg (dry weight)/kg-day for avian receptors exposed to zinc. Reproduction is the endpoint for the study upon which both TRVs is based. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

Mammalian Receptors

The U.S. EPA, Region 9 identifies a low end TRV of 9.6 mg (dry weight)/kg-day and a high end TRV of 411 mg (dry weight)/kg-day for mammalian receptors exposed to zinc.

The low end TRV is based on effects to kidneys and adrenal cortex. The high end TRV is based on developmental effects. The low end and high end values identified by U.S. EPA, Region 9 are selected as the TRVs for Step 3a.

HIGH MOLECULAR WEIGHT PAHs

Avian Receptors

The U.S. EPA, Region 9 does not identify TRVs for avian receptors exposed to HMW PAHs. The ECO-SSL source document for PAHs (U.S. EPA, 2007) states that only one study was identified that met the criteria for development of a TRV. This study identifies a NOAEL of 2.0 mg (dry weight)/kg-day and a LOAEL of 20 mg (dry weight)/kg-day. The test endpoint of the study was growth and the exposure route was gavage. Sample et al. (1996) do not identify TRVs for HMW PAHs. The NOAEL of 2.0 mg (dry weight)/kg-day and a LOAEL of 20 mg (dry weight)/kg-day are selected as the low end and high TRVs, respectively.

Mammalian Receptors

The U.S. EPA, Region 9 does not identify TRVs for mammalian receptors exposed to HMW PAHs. The ECO-SSL for mammalian receptors exposed to HMW PAHs is based on a TRV of 0.615 mg/kg-day. This TRV is the highest bounded NOAEL below the lowest bounded LOAEL for effects on reproduction, growth, or survival. This conservative TRV of 0.615 mg(dry weight)/kg-day is selected as the low end TRV for mammalian receptors.

The high end TRV for mammalian receptors was derived based on data presented in Table 6.1 of U.S. EPA (2007). The studies identified in Table 6.1 report results for a variety of test endpoints and exposure routes. Reproduction, growth, and survival are the endpoints most relevant to ecological risk assessment. The exposure route most relevant to ecological risk assessment is ingestion of HMW PAHs in food. Studies conducted on PAHs actually detected at the site (e.g., benzo(a)pyrene) were also considered. Based on these selection criteria, ten studies reported NOAELs and/or LOAELs that can be used to derive a high end TRV. The LOAELs, which are reported for six of the six studies, range from 3.07 mg (dry weight)/kg-day to 118 mg (dry weight)/kg-day. The geometric mean of the LOAELs for the six studies, 28.6 mg (dry weight)/kg-day, is selected as the high end TRV for HMW PAHs.

ACETONE

Avian Receptors

The U.S. EPA, Region 9 does not identify TRVs for avian receptors exposed to acetone. An ECO-SSL has not been developed for avian receptors. Sample et al. (1996) do not identify a TRV for avian receptors. U.S. EPA guidance for conducting ecological risk assessment at combustion facilities (U.S. EPA, 1999) identifies a TRV of 5.2 mg (wet weight)/kg-day for avian receptors based on a NOAEL for a study using Coturnix quail as the test organism. This value is the selected as the low end TRV for avian receptors.

The TRV of 5.2 mg (wet weight)/kg-day identified by U.S. EPA (1999) is a NOAEL, with an uncertainty factor of 100 applied. The NOAEL of the source study, 520 mg (wet weight)/kg-day, is selected as the high end TRV.

Mammalian Receptors

The U.S. EPA, Region 9 does not identify TRVs for mammalian receptors exposed to acetone. An ECO-SSL for mammalian receptors has not been developed. Sample et al. (1996) identify a NOAEL of 10 mg (wet weight)/kg-day and a LOAEL of 50 mg (wet weight)/kg for acetone based on a study using rat as the test organism. The NOAEL of 10 mg/kg-day and LOAEL of 50 mg (wet weight)/kg-day are selected as the low end and high end TRVs, respectively.

BIS(2-ETHYLHEXYL)PHTHALATE

Avian Receptors

The U.S. EPA, Region 9 does not identify TRVs for avian receptors exposed to bis(2-ethylhexyl)phthalate. An ECO-SSL for avian receptors exposed to bis(2-ethylhexyl)phthalate has not been developed. Sample et al. (1996) identify a NOAEL of 1.1 mg/kg-day for bis(2-ethylhexyl)phthalate based on a study using ringed doves. The NOAEL of 1.1 mg/kg-day is selected as the low end TRV for the avian receptors.

Sample et al. (1996) do not identify a LOAEL for bis(2-ethylhexyl)phthalate. The U.S. EPA (1999) identifies a TRV of 0.111 mg (wet weight)/kg-day for avian receptors. This TRV is based on the NOAEL from the same study as identified by Sample et al. (1996), with an uncertainty factor of 10 applied. Due to the absence of a published LOEAL, a high end TRV for bis(2-ethylhexyl)phthalate is not identified for avian receptors.

Mammalian Receptors

The U.S. EPA, Region 9 does not identify TRVs for mammalian receptors exposed to bis(2-ethylhexyl)phthalate. An ECO-SSL for mammalian receptors has not been developed. Sample et al. (1996) identify a NOAEL of 18.3 mg (wet weight)/kg-day and a LOAEL of 183 mg (wet weight)/kg-day based on a study using mouse as the test organism. The NOAEL of 18.3 mg/kg-day and LOAEL of 183 mg (wet weight)/kg-day are selected as the low end and high end TRVs, respectively.

SUMMARY

Table 1 and Table 2 identify the low end and high end TRVs selected for avian and mammalian receptors, respectively. As identified in the tables and discussion above, the TRVs identified by U.S. EPA, Region 9 and derived from the ECO-SSL sources are based on ingestion on a dry weight basis, whereas the TRVs identified in Sample et al. (1999) and U.S. EPA (1999) are based on a wet weight basis. For the food chain models in Step 3a, ingestion and TRVs will be on a dry weight basis. The TRVs based on wet weight can be converted to dry weight, but is dependent on the water content of the diet (i.e., plants, soil invertebrates, small mammals). The appropriate conversions will be made and reported in the Step 3a document, as required.

REFERENCES

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U.S. Environmental Protection Agency. 2005a. Ecological Soil Screening Levels for Antimony. Interim Final. OSWER Directive 9285.7-61. Office of Solid Waste and Emergency Response. February 2005.

U.S. Environmental Protection Agency. 2005b. Ecological Soil Screening Levels for Barium. Interim Final. OSWER Directive 9285.7-63. Office of Solid Waste and Emergency Response. February 2005.

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TABLE 1
TOXICITY REFERENCE VALUES FOR AVIAN RECEPTORS
FORMER PLAINWELL, INC. MILL PROPERTY
PLAINWELL, MICHIGAN

COPEC	Low End TRV			High End TRV		
	Value (mg/kg-day)	Weight Basis	Source	Value (mg/kg-day)	Weight Basis	Source
<u>Metals</u>						
Antimony	n/a	---	---	n/a	---	---
Barium	20.8	Wet	Sample et al. (1996)	41.7	Wet	Sample et al. (1996)
Cadmium	0.7	Dry	U.S. EPA, Region 9	10.4	Dry	U.S. EPA, Region 9
Copper	2.3	Dry	U.S. EPA, Region 9	52.3	Dry	U.S. EPA, Region 9
Iron	n/a	---	---	n/a	---	---
Lead	0.014	Dry	U.S. EPA, Region 9	8.75	Dry	U.S. EPA, Region 9
Mercury	0.039	Dry	U.S. EPA, Region 9	0.18	Dry	U.S. EPA, Region 9
Selenium	0.23	Dry	U.S. EPA, Region 9	0.93	Dry	U.S. EPA, Region 9
Zinc	17.2	Dry	U.S. EPA, Region 9	172	Dry	U.S. EPA, Region 9
<u>PAHs</u>						
HMW PAHs	2.0	Dry	U.S. EPA (2007)	20	Dry	U.S. EPA, 2007
<u>Organics</u>						
Acetone	5.2	Wet	U.S. EPA (1999)	520	Wet	U.S. EPA (1999)
BEHP	1.1	Wet	Sample et al. (1996)	n/a	---	---

Notes:

n/a - TRV not available

BEHP - Bis(2-ethylhexyl)phthalate

COPEC - Constituent of Potential Ecological Concern

HMW - High Molecular Weight

PAH - Polycyclic Aromatic Hydrocarbon

TRV - Toxicity Reference Value

U.S. EPA - United States Environmental Protection Agency

mg/kg-day - milligrams per kilogram per day

TABLE 2
TOXICITY REFERENCE VALUES FOR MAMMALIAN RECEPTORS
FORMER PLAINWELL, INC. MILL PROPERTY
PLAINWELL, MICHIGAN

COPEC	Low End TRV			High End TRV		
	Value (mg/kg-day)	Weight Basis	Source	Value (mg/kg-day)	Weight Basis	Source
<u>Metals</u>						
Antimony	0.059	Dry	U.S. EPA (2005a)	740	Dry	Derived - See Text for Discussion
Barium	51.8	Dry	U.S. EPA (2005b)	197	Dry	Derived - See Text for Discussion
Cadmium	0.06	Dry	U.S. EPA, Region 9	2.64	Dry	U.S. EPA, Region 9
Copper	2.67	Dry	U.S. EPA, Region 9	632	Dry	U.S. EPA, Region 9
Iron	n/a	---	---	n/a	---	---
Lead	1	Dry	U.S. EPA, Region 9	241	Dry	U.S. EPA, Region 9
Mercury	0.027	Dry	U.S. EPA, Region 9	4.0	Dry	U.S. EPA, Region 9
Selenium	0.05	Dry	U.S. EPA, Region 9	1.21	Dry	U.S. EPA, Region 9
Zinc	9.6	Dry	U.S. EPA, Region 9	411	Dry	U.S. EPA, Region 9
<u>PAHs</u>						
HMW PAHs	0.615	Dry	U.S. EPA (2007)	28.6	Dry	Derived - See Text for Discussion
<u>Organics</u>						
Acetone	10	Wet	Sample et al. (1996)	50	Wet	Sample et al. (1996)
BEHP	18.3	Wet	Sample et al. (1996)	183	Wet	Sample et al. (1996)

Notes:

n/a - TRV not available

BEHP - Bis(2-ethylhexyl)phthalate

COPEC - Constituent of Potential Ecological Concern

HMW - High Molecular Weight

PAH - Polycyclic Aromatic Hydrocarbon

TRV - Toxicity Reference Value

U.S. EPA - United States Environmental Protection Agency

mg/kg-day - milligrams per kilogram per day